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| APPLICATION NO.                                                    | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.      | CONFIRMATION NO.       |
|--------------------------------------------------------------------|-------------|----------------------|--------------------------|------------------------|
| 10/569,234                                                         | 01/29/2007  | Lindsey Jane Hudson  | 1300-1-014PCT/US         | 7475                   |
| 23565                                                              | 7590        | 05/20/2009           |                          |                        |
| KLAUBER & JACKSON<br>411 HACKENSACK AVENUE<br>HACKENSACK, NJ 07601 |             |                      | EXAMINER<br>GUSSOW, ANNE |                        |
|                                                                    |             |                      | ART UNIT<br>1643         | PAPER NUMBER           |
|                                                                    |             |                      | MAIL DATE<br>05/20/2009  | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                        |                      |  |
|------------------------------|------------------------|----------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 10/569,234             | HUDSON, LINDSEY JANE |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>      |  |
|                              | ANNE M. GUSSOW         | 1643                 |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 7-26 is/are pending in the application.
- 4a) Of the above claim(s) 7-18 and 24-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                      |                                                                   |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____                                                          | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. No claims have been amended.

Claims 1-6 and 27 have been cancelled.

Claims 7-18 and 24-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 12, 2008.

2. Claims 19-23 are under examination.

### ***Objections Withdrawn***

3. The objections to the title and the specification have been withdrawn in view of applicant's amendment to the title and the specification.

### ***Objections Maintained***

4. The objections to the drawings are maintained. Applicant's response filed January 12, 2009 included statements regarding replacement drawings however, no replacement drawings have been received.

***Rejections Maintained***

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The rejection of claims 19-23 under 35 U.S.C. 102(a, e) as being anticipated by Monahan, et al. is maintained.

Applicant's response filed January 12, 2009 has been fully considered by the examiner but is deemed not to be persuasive. The response states that Monahan et al. teach at paragraph [0068] that Table 1 provides markers that are over- expressed in ovarian cancer cells compared to normal ovarian cells. Table 1 on pages 7-10 lists hundreds of proteins, each of which is alleged to be a marker of ovarian cancer. However, Monahan et al. do not provide any data showing that the plethora of proteins listed in Table 1 is a marker for ovarian cancer. Applicant refers to the Examples on pages 40-41 where the total expression levels of ovarian cancer cell clones are compared to normal cell clones, and after selecting higher expressing ovarian cancer

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cell clones, the protein-encoding transcript sequences were determined. (See, paragraph [0335]) Taqman expression levels are only provided for OV88 protein on page 41. Accordingly, Monahan et al. do not provide any evidence that any one of the remaining hundreds of proteins listed in Table 1 is either over-expressed or under-expressed in ovarian cancer. Therefore, Monahan et al. fail to teach that any one of the remaining proteins of Table 1 may be used as an ovarian cancer marker for diagnosis. In short, one of ordinary skill in the art could not diagnose cancer by detecting one protein, MAL2 expression, without undue experimentation in view of the teachings of Monahan et al. (See response page 5).

In response to this argument, as applicant asserts, table 1 of Monahan, et al. teaches markers that are over expressed in ovarian cancer cells compared to normal ovarian cells. Thus, one of ordinary skill in the art would be able to determine an overexpression of the MAL2 polypeptide compared to a normal cell would indicate ovarian cancer.

A prior art reference provides an enabling disclosure and thus anticipates a claimed invention if the reference describes the claimed invention in sufficient detail to enable a person of ordinary skill in the art to carry out the claimed invention; "proof of efficacy is not required for a prior art reference to be enabling for purposes of anticipation." *Impax Labs. Inc. v. Aventis Pharm. Inc.*, 468 F.3d 1366, 1383, 81 USPQ2d 1001,1013 (Fed. Cir. 2006). (MPEP 2121 III).

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention not novel' or anticipated' within section 102, the stated test is

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whether a reference contains an enabling disclosure'... ." In re Hoeksema, 399 F.2d269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). (MPEP 2121.01) In the instant case Monahan, et al. discloses MAL2 polypeptide as being overexpressed in ovarian cancer cells compared to normal ovarian cells. Thus, one of ordinary skill in the art would be able to use the MAL2 polypeptide to detect overexpression and diagnose ovarian cancer.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

7. The rejection of claims 19-23 under 35 U.S.C. 102(b) as being anticipated by Ruben, et al. is maintained.

Applicant's response filed January 12, 2009 has been fully considered by the examiner but is deemed not to be persuasive. The response states that Ruben et al. provide a purely speculative disclosure of a vast number of proteins and their possible roles in diagnostic and therapeutic methods. Applicant refers to pages 28-31 where Ruben et al. teach that the Mal-a protein plays a role in a vast number of different cancers, immune system disorders, neurodegenerative disorders, behavioral disorders and other diseases. However, Ruben et al. provide no evidence of the role of the Mal-a protein in any disease. Regarding cancer, Ruben et al. teach that Mal-a is present at elevated levels in a number of cancers including cancers of the ovary, colon, lung and prostate. However, Ruben et al. provide absolutely no data to substantiate this allegation. Ruben et al. only provide examples that are merely details of methods that may be performed and are purely speculative. Therefore, Ruben et al. fail to teach that MAL2 may be used as an ovarian cancer marker for diagnosis. In short, one of ordinary skill in the art could not diagnose cancer by detecting one protein, MAL2 expression, without undue experimentation in view of the teachings of Ruben et al. (see response pages 5-6).

In response to this argument, Ruben, et al. discuss ovarian cancer as one of the cancers in which Mal-a is overexpressed. The instant claims require as an active step the detection of MAL2 polypeptide expression. There are no other active method steps in the claims directly related to ovarian cancer. Thus, the detection of the

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overexpression of MAL-a by Rube, et al. anticipates the detection of ovarian cancer in the instant claims. Detection of the overexpression of MAL-a would necessarily detect ovarian cancer since MAL-a overexpression is associated with ovarian cancer as taught by Ruben, et al.

Therefore, after a fresh consideration of the claims and the evidence provided the rejection is maintained.

### ***Conclusion***

8. No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.



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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNE M. GUSSOW whose telephone number is (571)272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow  
May 19, 2009

/David J Blanchard/  
Primary Examiner, Art Unit 1643